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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,304

03/10/2004

Daryl R. Kipke

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EXAMINER

EREZO, DARWIN P

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/797,304

Applicant(s)

KIPKE ET AL.

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office action is in response to the applicant's amendment filed on 9/5/08.

#### ***Drawings***

2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claims 1, 3-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,366,326 to Barry et al. and in view of US 20001/0031978 to Kipke et al.

(claim 1) Barry discloses a method of sealing the site of a neurosurgical procedure (col. 2, ll. 30-43) comprising the steps of: applying a purified alginate solution to a site of a neurosurgical procedure and adding a calcium chloride solution to form a polymer (col. 3, ll. 39-45). Barry does not disclose the purified alginate solution having a G/M ratio greater than 60/40. However, Kipke discloses that it is known to use purified alginate solution having a G/M ratio greater than 60/40 as a medical occluder (paragraph [0042]). Therefore, it would have been obvious to one of ordinary skill in the art to modify the methodology of Barry to use a purified alginate solution having a G/M ratio greater than 60/40 because Kipke discloses that such a ratio is well known in the

art, and it has been held that the use of a known technique (the G/M ratio) to improve similar devices will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007). That is, the benefits of using a high G alginate in the device of Kipke would also benefit the device of Barry.

(claims 3, 5 and 6) Barry discloses the site to be the central nervous system, more specifically to the spinal cord of a human being(col. 2, ll. 32).

(claim 4) Barry discloses all the limitations of the claim except for the site being the brain. Barry does disclose the site being the spinal cord. Thus, one of ordinary skill in the art would have found it obvious to use the methodology of Barry to treat the brain during a neurosurgical procedure since both the brain and the spinal cord are both part of the central nervous system and that the use of a known technique to treat similar sites would provide predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

(claims 7 and 8) Barry discloses the alginate solution to have a molecular weight of 1,000 to 3,000,000 daltons (or 1,000 to 3,000,000 g/mol), which covers the range recited by the applicant . Barry also discloses the concentration to be about 0.1% to 4%, which covers the range recited by the applicant (col. 4, ll. 52-57).

(claim 9) Barry discloses the use of guluronic acid content alginate (col. 4, ll. 3) but is silent with regards to the viscosity range. However, one of ordinary skill in the art would have found it obvious to use the alginate in a viscosity of 20 mPas to about 200 mPas since it has been held that where the general conditions of a claim are disclosed

in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

(claim 10) Barry discloses the additional use of drugs (col. 6, ll. 53-55).

(claim 11) Barry discloses the use of 2% calcium chloride (col. 6, ll. 14).

(claim 12) See the rejection to claim 1. The addition of an alginate solution and calcium chloride to form a polymer would provide a visual location of the site of the neurosurgical procedure.

(claim 14) See the rejection to claim 3.

7. Claims 2, 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. in view of Kipke et al., as applied to the rejection to claims 1 and 12 above, and in further view of US 5,433,739 to Sluijter et al.

(claims 2 and 13) The modified methodology of Barry discloses all the limitations of the claim, including the neurosurgical procedure being a laminectomy procedure. Barry is silent with regards to the neurosurgical procedure comprising the implantation of a neural probe. However, Sluijter discloses that the insertion of a neural probe is common during a laminectomy procedure (col. 13, ll. 15-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the step of implanting a neural probe to the methodology of Barry because it is known in the art to implant a neural probe during a laminectomy procedure, as taught by Sluijter.

(claims 15 and 16) See the rejection to claim 1. The formation of a polymer formed from alginate solution and calcium chloride would inherently stabilize the neural probe. The site of the neurosurgical procedure is the central nervous system.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erez/  
Primary Examiner, Art Unit 3773